



products are currently marketed in the United States, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1 of the Complaint and, therefore, denies them.

### **THE PARTIES**

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and, therefore, denies them.

3. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint and, therefore, denies them.

4. Lupin admits that Lupin Limited is a company organized and existing under the laws of India, has a place of business at Laxmi Towers “B” Wing, 5<sup>th</sup> Floor, Bandra Kurla Complex, Mumbai 400 051, India, and has a registered office at 159 C.S.T. Road, Kalina, Santacruz (East), Mumbai 400 098, India. Lupin further admits that Lupin Limited manufactures and sells pharmaceutical products through subsidiaries, including through LPI, but denies the remaining allegations in paragraph 4 of the Complaint.

5. Lupin admits that LPI is a corporation organized and existing under the laws of the State of Virginia, and has a place of business at Harborplace Tower, 111 South Calvert Street, 21<sup>st</sup> Floor, Baltimore, Maryland 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that LPI sells pharmaceutical products for the United States market. Lupin denies the remaining allegations in paragraph 5 of the Complaint.

### **JURISDICTION AND VENUE**

6. For the purposes of this action only, Lupin Limited does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). LPI, however, is not a proper party to

this action, and therefore Lupin denies the remaining allegations in paragraph 6 of the Complaint.

7. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin Limited. Lupin denies the remaining allegations in paragraph 7 of the Complaint.

8. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI. Lupin denies the remaining allegations in paragraph 8 of the Complaint.

9. Lupin admits that LPI is designated as Lupin Limited's U.S. agent in Lupin Limited's ANDA No. 200750 which seeks FDA approval to market fenofibrate choline DR capsules in the United States. Lupin denies the remaining allegations in paragraph 9 of the Complaint.

10. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that the Lupin Limited 2008 Annual Report includes information concerning LPI. Lupin denies the remaining allegations in paragraph 10 of the Complaint.

11. Lupin admits the allegations in paragraph 11 of the Complaint.

12. Lupin admits the allegations in paragraph 12 of the Complaint.

13. Paragraph 13 states legal conclusions to which no answer is required. To the extent an answer to any factual allegations is required, Lupin Limited and LPI do not contest that this Court has personal jurisdiction over them for the limited purposes of this action only. Lupin denies any remaining allegations in paragraph 13 of the Complaint.

14. Lupin does not contest venue in this action.

### **BACKGROUND**

15. Lupin admits that U.S. Patent No. 7,259,186 (“the ’186 patent”) is titled “Salts of Fenofibric Acid and Pharmaceutical Formulations Thereof,” and that a copy thereof is alleged to be attached as Exhibit A to the Complaint. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 of the Complaint and, therefore, denies them.

16. Paragraph 16 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are set forth in paragraph 16 of the Complaint, Lupin denies them.

17. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint and, therefore, denies them.

18. Lupin admits that TRILIPIX® is approved for marketing by the FDA, but is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Complaint and, therefore, denies them.

19. Lupin admits that TRILIPIX® is included in the Orange Book. The remainder of paragraph 19 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions remain in paragraph 19 of the Complaint, Lupin denies them.

20. Lupin admits that the ’186 patent is listed in the Orange Book in association with TRILIPIX®. The remainder of paragraph 20 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions remain in paragraph 20 of the Complaint, Lupin denies them.

21. Lupin admits that LPI is a wholly-owned subsidiary of Lupin Limited, and that Lupin Limited submitted ANDA No. 200750 to the FDA which seeks approval to market

fenofibrate choline DR capsules in the United States before the expiration of the '186 patent. Lupin further admits that LPI or a designee plans to market the fenofibrate choline DR capsules in the United States as soon as permitted to do so by any applicable statutes and regulations. Lupin denies the remaining allegations in paragraph 21 of the Complaint.

22. Lupin admits that, by letter dated February 9, 2010, Lupin Limited advised Plaintiffs that it submitted ANDA No. 200750 which seeks approval to market fenofibrate choline DR capsules in the United States before the expiration of the '186 patent. Lupin denies the remaining allegations in paragraph 22 of the Complaint.

23. Lupin admits that, by letter dated February 9, 2010, Lupin Limited advised Plaintiffs that ANDA No. 200750 included a certification under 21 U.S.C. 355(j)(2)(vii)(IV) that the '186 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the fenofibrate choline DR capsules that are the subject of ANDA No. 200750. Lupin denies the remaining allegations in paragraph 23 of the Complaint.

24. Lupin denies the allegations in paragraph 24 of the Complaint.

## **COUNT I**

### **Patent Infringement**

25. Lupin incorporates by reference its responses to paragraphs 1 to 18 of the Complaint as if fully set forth herein.

26. Paragraph 26 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 26 of the Complaint, Lupin denies them.

27. Paragraph 27 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 27 of the Complaint, Lupin denies them.

28. Paragraph 28 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 28 of the Complaint, Lupin denies them.

29. Paragraph 29 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 29 of the Complaint, Lupin denies them.

30. Paragraph 30 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 30 of the Complaint, Lupin denies them.

31. Paragraph 31 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 31 of the Complaint, Lupin denies them.

### **AFFIRMATIVE AND SEPARATE DEFENSES**

Without prejudice to the denials set forth in its responses to paragraphs 1 through 31 of the Complaint, Lupin alleges the following Affirmative and Separate Defenses to the Complaint.

#### **First Defense** **(Invalidity of the '186 patent)**

32. The '186 patent, and each of the claims 1 through 15 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

**Second Defense**  
**(Limitation of Remedies)**

33. The remedy of an injunction or other equitable relief sought by Plaintiffs in its Complaint is unavailable to Plaintiffs in this action.

**Third Defense**  
**(Subject Matter Jurisdiction)**

34. The Complaint fails to state a claim against LPI upon which relief can be granted.

**COUNTERCLAIMS**

35. Defendant/Counterclaim-Plaintiff Lupin Limited brings the following Counterclaims against Plaintiff/Counterclaim-Defendants Abbott Laboratories and Fournier Laboratories Ireland, Ltd. for a declaratory judgment that the '186 patent is invalid and/or not infringed by the fenofibrate choline DR capsules that are the subject of ANDA No. 200750.

**THE PARTIES**

36. Counterclaim-Plaintiff Lupin Limited is corporation organized and existing under the laws of India having a place of business at Laxmi Towers "B" Wing, 5<sup>th</sup> Floor, Bandra Kurla Complex, Mumbai 400 051, India, and has a registered office at 159 C.S.T. Road, Kalina, Santacruz (East), Mumbai 400 098, India.

37. Upon information and belief, Counterclaim-Defendant Abbott Laboratories is a corporation organized under the laws of the State of Illinois, having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

38. Upon information and belief, Counterclaim-Defendant Fournier Laboratories Ireland, Ltd. is an Irish corporation having its principal place of business at Anngrove, Carrigtwohill, Co. Cork, Ireland.

### **JURISDICTION AND VENUE**

39. Plaintiffs have brought an action against Lupin Limited for allegedly infringing the '186 patent. There exists an actual case or controversy between Lupin Limited and Plaintiffs as to Lupin Limited's alleged infringement of the '186 patent.

40. This Court has subject matter jurisdiction over a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a) and 1367, based on an actual controversy between Lupin Limited and Counterclaim Defendants Abbott Laboratories and Fournier Laboratories Ireland, Ltd. arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

41. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b). Venue also is proper as a result of the filing of the present action by Plaintiffs against Lupin Limited in this judicial district.

### **FIRST COUNT** **(Declaration of Invalidity of the '186 Patent)**

42. Lupin Limited incorporates the allegations set forth in paragraphs 35 through 41 of the Counterclaims as if fully set forth herein.

43. The '186 patent, including claims 1 through 15 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

44. There is an actual case or controversy as to the invalidity of claims 1 through 15 of the '186 patent.

### **SECOND COUNT** **(Declaration of Noninfringement of the '186 Patent)**

45. Lupin Limited incorporates the allegations set forth in paragraphs 35 through 44 of the Counterclaims as if fully set forth herein.



46. The claims of the '186 patent, including claims 1 through 15 thereof, will not be infringed by the manufacture, use, sale, offer for sale, or importation of the fenofibrate choline DR capsules (45 mg and 135 mg) that are the subject of ANDA No. 200750.

47. There is an actual case or controversy as to the infringement of claims 1 through 15 of the '186 patent.

**THIRD COUNT**  
**(Exceptional Case)**

48. Lupin Limited incorporates the allegations set forth in paragraphs 35 through 47 of the Counterclaims as if fully set forth herein.

49. At the time Plaintiffs filed the Complaint, Plaintiffs had not made a good faith inquiry into their allegations against Lupin Limited for infringement of the '186 patent.

50. At the time Plaintiffs filed the Complaint, Plaintiffs had no objectively reasonable basis for charging Lupin Limited with infringement of the '186 patent.

51. This action is an exceptional case within the meaning of 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Lupin Limited prays that this Court enter a judgment against Plaintiffs:

A. Declaring that the claims of the '186 patent are not and would not be infringed by Lupin Limited;

B. Declaring that the claims of the '186 patent are not and would not be infringed by the fenofibrate choline DR capsules that are the subject of ANDA No. 200750;

C. Declaring that the claims of the '186 patent are invalid;

D. Determining that, under 35 U.S.C. § 285, this is an "exceptional case" and awarding Lupin Limited its attorneys' fees in this action;

- E. Awarding Lupin Limited its costs and expenses incurred in this action; and
- F. Awarding Lupin Limited such other and further relief as the Court may deem proper.

**STERNS & WEINROTH, P.C.**

Dated: May 5, 2010

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 AND 40.1  
OF LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.**

Pursuant to Local Civil Rule 11.2 and 40.1, Defendants Lupin Limited and Lupin Pharmaceuticals, Inc., by their attorneys, hereby certify to the best of their knowledge and belief that the matter in controversy, particularly the patent-in-suit (U.S. Patent No. 7,259,186) in the above-captioned matter, is the subject of the following action: Abbott Laboratories, et al. v. Impax Laboratories, Inc., 10cv1322 (DMC)(CCC).

/s/ Karen A. Confoy  
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Dated: May 5, 2010